Hyperbaric Oxygen Therapy for the Treatment of Perianal fistulas In Crohn’s disease

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Hyperbaric Oxygen Therapy is an effective and feasible therapy option for therapy-refractory patients with perianal fistulas in Crohn's disease.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23412

Bron
NTR

Verkorte titel
HOT-TOPIC trial

Aandoening

Crohn's disease, Morbus Crohn, perianal fistula(s), fistulising Crohn's disease, inflammatory bowel disease, IBD.
Ziekte van Crohn, perianale fistels, fistelende ziekte van Crohn, inflammatoire darmziekte.

Ondersteuning

Primaire sponsor: Academic Medical Centre, Amsterdam
Overige ondersteuning: Academic Medical Centre, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Co-primary parameters:
- Perianal disease activity index (PDAI) as assessed by the primary physician (gastroenterologist or surgeon) and patient.
- MRI-imaging, assessed by an independent radiologist using the (modified) van Assche score.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients will be recruited through the outpatient fistula clinic in the AMC. Patients that are willing to participate will be asked whether they want to receive hyperbaric oxygen therapy or if they want to serve as a controlgroup, continuing to receive standard care. If they choose to undergo hyperbaric oxygen therapy (n = 20) treatment will start directly at the beginning of the study and will last for 8 weeks (= 40 sessions). After 30 sessions the seton will be removed. Patients will be followed until 1 year after treatment, using the earlier mentioned parameters/outcomes. The control group will be followed for the same period of time, but without MRI or labwork. If patients refuse hyperbaric oxygen therapy or participation, they will be asked for their reasons for refusal (in regards to feasibility).

Doel van het onderzoek

Hyperbaric Oxygen Therapy is an effective and feasible therapy option for therapy-refractory patients with perianal fistulas in Crohn's disease.

Onderzoeksopzet

HBO therapy will start directly a the beginning of the study, week 0-8. Timepoints for HBO group:

PDAI: baseline, week 16, 34 and 60.

MRI: baseline, week 16 and 60.

FDA: baseline, week 16, 34 and 60.

Labwork: baseline, week 16, 34 and 60.

PROs: baseline, week 16, 34 and 60.

The parameters and timepoints for the control group are:

PDAI: baseline, week 16, 34 and 60.

FDA: baseline, week 16, 34 and 60.

PROs: baseline, week 16, 34 and 60.

Onderzoeksproduct en/of interventie

Hyperbaric oxygen (HBO) group: a total of 40 sessions of HBO, 30 before the removal of the seton and 10 after. One session consists of a total of 80 minutes of 100% oxygen with 5-minute airbreaks, with a total session time of 110 minutes. The pressure that will be used is 2.4-2.5 atmosphere absolute.

Control group: standard care (medical or surgical) as deemed necessary by the primary physician (gastroenterologist and/or surgeon).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Confirmed diagnosis Crohn’s disease

- Actively draining high perianal fistula (>1/3 through external sphincter), regardless of number

- Failure of treatment with standard care (medical and/or surgical) > 6 months or intolerance to standard treatment

- Standard care treatment regimen has been stable for at least six weeks

- > 18 years

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unfit for hyperbaric oxygen therapy as assessed by the hyperbaric physician

- Language barrier

- Unable to give informed consent

- Patients without a seton

- Patients with a seton in situ > 12 months

- Patients with anal stricture

- Patients with rectovaginal fistulas

- Patients with stoma

- Patients with deep ulcers in the rectum

- Presence of fluid collection/abscess that needs to be surgically drained

- Prior surgical procedure in the preceding 3 months

- Patients with a contraindication to undergo MRI (claustrophobia, intravenous contrast allergy)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-09-2017
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	06-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47818
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6489
NTR-old	NTR6676
CCMO	NL60640.018.17
OMON	NL-OMON47818

Resultaten

Samenvatting resultaten
N.A.